K010799

JUN - 7 2001

WORLD HEADQUARTERS
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CINCINNATI, OHIO
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510(k) Summary

This summary of 510(k) safety and effectiveness is being supplied in accordance with the Safe Medical Device Act of 1990 and 21 C.F.R.

807.92(a)

1. Standard Textile Co., Inc.
One Knollcrest Drive
Cincinnati, Ohio 45237

Contact Person: Brad Bushman
(513) 761-9255 Ext. 455
Summary Prepared on 3/9/01

2. Device Name: COMBOsafe™ Surgical Gowns, non-sterile (75X reusable)

Common/Usual Name: Surgical Gown

Classification Name: Surgical Apparel 21 C.F.R. § 878.4040

3. Predicate Device: ComPel XTR® Surgical Gowns #K922753

4. All fabric components used in COMBOsafe™ Surgical Gowns are made from 100% polyester, dyed blue/sage green and are laminated with a urethane film.

COMBOsafe Surgical Gowns will function as surgical gowns when processed according to instructions through 75 complete wash, dry and sterilization cycles. These products will be manufactured and distributed as non-sterile surgical gowns that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies.

5. COMBOsafe Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patients and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

There are no critical differences in the use of this product from currently marketed ComPel XTR® Surgical Gowns except for higher liquid resistance and sleeve seam performance claims. COMBOsafe Surgical Gowns have demonstrated that they will perform as intended when used as labeled.

6. The tests that have been successfully completed include:

a. Flammability 16 CFR Part 1610.

b. Barrier Performance
   i. Suter Hydrostatic Testing AATCC #127-1989
   ii. Mullens Hydrostatic Testing ASTM D751-95 Procedure A

c. Strength ASTM #D-1682-87

d. Lint EDANA 220.0-96

e. Toxicity - Cytotoxicity MEM Elution (MG023)
Acute Systemic Toxicity (ISO 10993)

f. Primary Skin Irritation (ISO 10993))

g. Sterilization - Product sold non-sterile; can be sterilized using prevacuum steam cycles.

h. Durability through 75 processing (wash, dry and sterilization).

i. Colorfastness to Commercial Laundering - AATCC #61-1993(4A).

To the best of my knowledge, all data and information in the 510(k) are truthful and accurate, and that no material fact has been omitted.

5/14/01

Bradley J. Bushman

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2001

Mr. Bradley J. Buschman
Director of Technical Resources
Standard Textile Company, Incorporated
One Knollcrest Drive
P.O. Box 371805
Cincinnati, Ohio 45237-1600

Re: K010799
Trade/Device Name: COMBOsafe Surgical Gowns, Non-Sterile (75x reusable)
Regulation Number: 878.4040
Regulatory Class: II
Product Code: FYA
Dated: May 14, 2001
Received: May 18, 2001

Dear Mr. Buschman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER: k010799

DEVICE NAME: COMBOsafe Surgical Gowns, non-sterile (75X Reuse)

INDICATIONS FOR USE:

COMBOsafe Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patients and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

COMBOsafe Surgical Gowns will function as surgical gowns when processed according to instructions. The COMBOsafe Surgical Gowns are reusable and are manufactured and distributed as non-sterile surgical gowns that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ (Per 21 CFR 801.109) OR Over-The-Counter-Use X (Optional Format 1)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010799